No.

IN THE

Supreme Court of the United States

JOHNSON & JOHNSON, a New Jersey Corporation;
ETHICON, INC., a New Jersey Corporation;
AND ETHICON US, LLC,

Petitioners,

v.

STATE OF CALIFORNIA,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO
THE CALIFORNIA COURT OF APPEAL

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

1. Whether a robust fair notice standard applies to California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 et seq., and False Advertising Law, Cal. Bus. & Prof. Code § 17500 et seq., given the severe civil penalties at stake, the risk of chilling protected speech, and the criminal penalties involved.

2. Whether Ethicon had fair notice that it faced hundreds of millions of dollars in civil penalties under these statutes for materials sent to California, but not proven to have reached consumers.

PARTIES TO THE PROCEEDINGS

Petitioners Johnson & Johnson, Ethicon, Inc., and Ethicon US, LLC were defendants-appellants below.

Respondent the State of California was plaintiff-respondent below.

CORPORATE DISCLOSURE STATEMENT

1. Johnson & Johnson is a publicly held company. It has no parent corporation, and no publicly held company owns 10% or more of Johnson & Johnson's stock.

2. Ethicon, Inc. is wholly owned by Johnson & Johnson, which is a publicly held company.

3. Ethicon US, LLC is wholly owned by Ethicon Endo-Surgery, Inc. Ethicon Endo Surgery, Inc. is wholly owned by Ethicon, Inc. Ethicon, Inc. is wholly owned by Johnson & Johnson, which is a publicly held company.

RELATED PROCEEDINGS

People v. Johnson & Johnson, No. S274680 (California Supreme Court) (order denying petition for review issued July 13, 2022).

People v. Johnson & Johnson, No. D077945 (California Court of Appeal, Fourth Appellate District) (order modifying opinion and denying rehearing issued April 27, 2022).

People v. Johnson & Johnson, No. 37-2016-00017229 (California Superior Court, County of San Diego) (final judgment issued August 6, 2020; order denying injunctive relief issued June 30, 2020, statement of decision issued January 30, 2020).

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INTRODUCTION

Businesses accused of failing to warn of a product's risks used to be able to rely on certain basic common law protections. Plaintiffs asserting such tort claims need to offer individualized proof of causation and actual injury. But states across the country have severely curtailed those protections with statutes that broadly prohibit unfair and deceptive acts and practices ("UDAP statutes"). These statutes transform what were previously ordinary product liability claims into massive claims that require no such individualized proof of injury or causation. Using these broad UDAP statutes, states can extract hundreds of millions of dollars at a time from businesses. And in the absence of traditional common law protections, companies struggle to predict their exposure.

This case is part of this dangerous trend. The California Attorney General asserted claims under California's Unfair Competition Law and False Advertising Law. It argued that statements made by Petitioners Johnson & Johnson, Ethicon, Inc., and Ethicon US LLC (for simplicity, "Ethicon") about mesh used in pelvic surgery were "likely to deceive" consumers and physicians. The California court counted up more than 200,000 statutory violations—based in significant part on communications not proven to have reached consumers at all. And the court awarded over $300 million in civil penalties for those "violations."

Ethicon lacked fair notice of the severity of this penalty. The California UDAP statutes do not define what constitutes a separate "violation" for purposes of penalty counting. Instead, courts answer this question on a case-by-case basis—they figure it out as they go. Of course, that leaves businesses in the dark.

Courts used to mitigate this problem slightly: only marketing materials *transmitted* to consumers counted as "violations" for penalties purposes. That made sense—only those communications were "likely to deceive" consumers. The California courts have now stripped away even that anemic guidance, however, by penalizing Ethicon for all marketing materials shipped to California—regardless of whether they ever made their way to doctors or consumers. This new rule is so divorced from basic concepts of deception and harm that no company in Ethicon's position could have predicted that result.

Large verdicts in cases involving similar UDAP statutes are proliferating across the country at the hands of state attorneys general and plaintiffs' lawyers seeking big pay days. This Court should grant review here and hold that constitutional due process limits these expansive state actions.

OPINIONS AND ORDERS BELOW

The California Supreme Court's order denying Ethicon's petition for review is reproduced in the Petition Appendix (Pet. App.) at 544a. The decision of the California Court of Appeal, as modified on denial of rehearing, is published at 292 Cal. Rptr. 3d 424, and reproduced at Pet. App. 1a-103a. The Superior Court's decision finding Ethicon liable and awarding civil penalties is reproduced at Pet. App. 113a-543a, and its order denying injunctive relief is reproduced at Pet. App. 109a-112a. The judgment of the Superior Court is reproduced at Pet. App. 104a-108a.

JURISDICTION

The California Supreme Court denied Ethicon's petition for review on July 13, 2022. Pet. App. 544a. On September 22, 2022, Justice Kagan granted Ethicon's application to extend the time to file a petition for a writ of certiorari to and including November 10, 2022. This Court has jurisdiction under 28 U.S.C. § 1257(a).

STATUTORY PROVISIONS INVOLVED

Section 17200 of California's Business and Professions Code, reproduced in full at Pet. App. 545a, provides in relevant part:

> [U]nfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by Chapter 1 (commencing with Section 17500) of Part 3 of Division 7 of the Business and Professions Code.

Section 17206 of California's Business and Professions Code, reproduced in full at Pet. App. 546a-549a, provides in relevant part:

> (a) Any person who engages, has engaged, or proposes to engage in unfair competition shall be liable for a civil penalty not to exceed two thousand five hundred dollars ($2,500) for each violation ….

> (b) The court shall impose a civil penalty for each violation of this chapter. In assessing the amount of the civil penalty, the court shall consider any one or more of the relevant circumstances presented by any of the parties to the case, including, but not limited to, the following: the nature and seriousness of the misconduct, the number of violations, the persistence of the misconduct, the length of time over which the misconduct occurred, the willfulness of the defendant's misconduct, and the defendant's assets, liabilities, and net worth.
>
> (c)(1) If the action is brought by the Attorney General, one-half of the penalty collected shall be paid to the treasurer of the county in which the judgment was entered, and one-half to the General Fund.

Section 17500 of California's Business and Professions Code, reproduced in full at Pet. App. 550a-551a, provides in relevant part:

> It is unlawful … to make or disseminate or cause to be made or disseminated before the public in this state … any statement … which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading…. Any violation of the provisions of this section is a misdemeanor punishable by imprisonment in the county jail not exceeding six months, or by a fine not exceeding two

thousand five hundred dollars ($2,500), or by both that imprisonment and fine.

Section 17536 of California's Business and Professions Code, reproduced in full at Pet. App. 552a-553a, provides in relevant part:

> (a) Any person who violates any provision of this chapter shall be liable for a civil penalty not to exceed two thousand five hundred dollars ($2,500) for each violation ….
>
> (b) The court shall impose a civil penalty for each violation of this chapter. In assessing the amount of the civil penalty, the court shall consider any one or more of the relevant circumstances presented by any of the parties to the case, including, but not limited to, the following: the nature and seriousness of the misconduct, the number of violations, the persistence of the misconduct, the length of time over which the misconduct occurred, the willfulness of the defendant's misconduct, and the defendant's assets, liabilities, and net worth.
>
> (c) If the action is brought by the Attorney General, one-half of the penalty collected shall be paid to the treasurer of the county in which the judgment was entered, and one-half to the State Treasurer.

STATEMENT OF THE CASE

Ethicon Makes Pelvic Mesh To Treat Women With Serious Health Conditions

Ethicon has developed pioneering treatments for two serious health conditions that afflict women: stress urinary incontinence (SUI) and pelvic organ prolapse (POP). Pet. App. 117a-119a. SUI is "a leakage of urine during moments of physical activity that increases abdominal pressure." U.S. FDA, *Stress Urinary Incontinence* (Apr. 2019), https://tinyurl.com/mvmftd7y. POP "occurs when the tissue and muscles of the pelvic floor no longer support the pelvic organs resulting in the drop (prolapse) of the pelvic organs from their normal position." U.S. FDA, *Pelvic Organ Prolapse* (Apr. 2019), https://tinyurl.com/mr26652n.

These medical conditions can dramatically affect the quality of a woman's life. Women with SUI can experience urine leakage when they laugh, cough, or exercise. Pet. App. 117a. And women with POP have weakened pelvic tissue and muscle, which can result in extreme health problems, including pain and organ prolapse into or outside of the vagina. *Id.*; U.S. FDA, *Pelvic Organ Prolapse*, *supra*.

Doctors may recommend surgery for POP based on several factors—including the severity of pain and discomfort, which organ(s) have prolapsed, and the severity of any prolapse. *See* U.S. FDA, *Pelvic Organ Prolapse*, *supra*. Similarly, they may recommend surgery for SUI based on the severity of the SUI symptoms and their effect on daily activities, among other factors. U.S. FDA, *Stress Urinary Incontinence*, *supra*.

Before mesh, surgical treatment options for SUI were highly invasive and carried severe risks. Pet. App. 119a; 20RT2158 (non-mesh surgical treatment for SUI requires "more dissection," "longer hospitalization," "longer recovery," and "more postoperative morbidity" than surgical treatment with mesh). Pre-mesh surgical options for POP likewise had risks of serious complications and low success rates. 50RT8440 (failure rate of non-mesh surgical treatment for POP was "50 percent or higher"); 50RT8436-37 (non-mesh surgical treatment option for POP could result in major complications, including "massive hemorrhage" and nerve damage).

Pelvic mesh devices—consisting of a piece of mesh that surgeons can implant in the body—provided a different option over non-mesh surgery. Pet. App. 6a. Ethicon produced the mesh in different shapes, which had different purposes. *Id*. To treat POP, Ethicon sold both mesh to implant in the pelvic floor (to support the pelvic organs) and instruments to facilitate the mesh placement. Pet. App. 6a-7a; 5AA1336. To treat SUI, Ethicon created a precut strip of mesh, with instruments for insertion and placement, that sits beneath the midurethra like a sling, and "pushes the urethra closed when pressure is exerted (e.g., during a cough) to stop urine leakage." Pet. App. 6a; 44RT7226; 6AA1892. "The use of surgical mesh slings to treat SUI provides a less invasive approach than non-mesh repairs, which require a larger incision in the abdominal wall." U.S. FDA, *Stress Urinary Incontinence*, *supra*.

The FDA Reviews Disclosures

All implanted medical devices and surgical procedures carry some degree of risk, and surgeries to implant pelvic mesh devices are no exception. Possible complications from pelvic surgery and mesh implantation include infection, pain, urinary problems, and vaginal exposure and erosion. Pet. App. 7a; *see* 22RT2674-75; 39RT6249-50.

The FDA has a clearance process for these devices. *See* 21 U.S.C. § 360(k); Pet. App. 74a-76a. For the mesh devices at issue, the FDA permitted clearance after a determination that the devices were substantially equivalent to a device already legally on the market. *See* 21 U.S.C. § 360c; Pet. App. 74a-76a. As part of that process in this case the FDA evaluated the mesh's design and its labeling. Pet. App. 75a-76a; *see* 21 C.F.R. § 807.87(e); 21 U.S.C. § 360c(i)(1)(A).

The boxes of pelvic mesh surgical devices include the device's FDA-required information packets—called "Instructions for Use" (IFUs)—directed at the surgeons who perform the POP and SUI mesh surgeries. The IFUs list proper uses of the mesh and potential adverse reactions that could result. Pet. App. 9a; *see* 21 C.F.R. § 801.109(c). Ethicon developed robust procedures to ensure that its IFUs adequately disclosed the risks of mesh implantation. In particular, risk statements in the IFUs were reviewed by Ethicon's multi-disciplinary teams, including professionals from the company's medical and regulatory affairs departments. *See* 33RT4838-39; 46RT7694-95; 45RT7412-13. Ethicon also incorporated feedback from outside surgeons and nurses. *See* 34RT5033-36;

44RT7304-06. Similarly, Ethicon closely vetted its educational and marketing materials through medical, legal, and regulatory teams. *See* 33RT4838; 45RT7488.

The FDA worked closely with Ethicon throughout this process. It typically spent several months reviewing each pelvic mesh product, and sent suggestions and concerns to Ethicon. *E.g.*, JX10016 (Ethicon's October 1997 510(k) notification), JX10017 (FDA's required changes), 14AA3630-31 (FDA's clearance of device for marketing months later, in January 1998). The FDA's review of Ethicon's POP mesh devices in 2007-08 lasted almost a year. *See* 15AA3664-74; 53RT8801. The FDA cleared Ethicon's pelvic mesh products only after conducting those reviews—in 1998, 2002, 2003, 2005, 2007, 2008, and 2010. 14AA3630, 14AA3633, 15AA3647, 15AA3650, 15AA3655, 15AA3658, 15AA3661, 15AA3673.

Given this deep involvement, the FDA at times weighed in directly on the warning language for surgeons. For example, when Ethicon sought clearance for its pelvic mesh device in 1997, the FDA asked Ethicon to include additional potential risk information. *See* JX10016, JX10017. Ethicon made those changes, and the FDA then cleared the product for sale and use. JX10018; 14AA3630. Ethicon incorporated extensive feedback from the FDA in connection with the FDA's 2007-08 review of POP IFUs and related patient brochures. Pet. App. 75a-76a; 15AA3664-69.

Ethicon Reaches Out To The Public

Public knowledge about treatments for POP and SUI is limited in part because people with these health conditions can sometimes be embarrassed to talk about them. 33RT4955; 40RT6380; 41RT6647. Ethicon sought to enhance public knowledge, providing information about the diseases and treatment options. 33RT4955-56; 45RT7495. For example, Ethicon created materials that helped women identify symptoms, informed them that these conditions are treatable, and aimed "to open up the conversation" with doctors and healthcare professionals. 33RT4957; *see* 33RT4954-55. Further, Ethicon developed model questions a woman could use to guide a conversation with her doctor, designed to "help make that conversation a bit easier." 33RT4957-58. The company also produced anatomical diagrams to illustrate to potential patients how mesh procedures work. 19AA4216; *see* 40RT6394-96.

In addition, Ethicon educated patients and doctors about its new treatment options. This included sending sales representatives to doctors, who sometimes invited the representatives to observe in operating rooms, and advertising in medical journals. Pet. App. 122a, 203a; 37RT5808, 37RT5810. Ethicon also informed patients and doctors by distributing brochures, advertising online, and operating a telephone hotline. Pet. App. 121a. As required by the FDA, Ethicon included IFUs with the devices. Pet. App. 120a, 9a.

The FDA Issues Information About Mesh Safety

The FDA has issued several public health notifications about pelvic mesh, which inform the public about the potential risks associated with pelvic mesh implantation surgery. In 2008, the FDA issued a notification, warning that in rare cases SUI and POP pelvic mesh implants could result in serious complications requiring additional surgery—and that the surgery might not correct the problem. Pet. App. 129a-130a; 14AA3562. Later, in 2011, the FDA warned that, contrary to its prior statement, complications associated with POP pelvic mesh implants were not rare. Pet. App. 133a.

Ethicon subsequently chose to stop selling all but one of its POP pelvic mesh products, and to limit the use of the remaining device. Pet. App. 134a-135a. Ethicon's competitors continued to sell POP pelvic mesh products. *See* Pet. App. 8a. Thereafter, in 2016, the FDA reclassified the transvaginal POP mesh devices as Class III devices, and later ordered manufacturers to stop selling and distributing them unless the companies obtained approval from the FDA under that new classification. Pet. App. 136a-137a; 26AA5498.

As for the SUI pelvic mesh products, the FDA released a 2013 update finding the safety and effectiveness of SUI mesh devices well-established for up to a year after surgery. Pet. App. 135a. In 2015, Ethicon revised its SUI device IFUs at the request of the Canadian health authority, to include additional adverse events. Pet. App. 135a-136a.

The California Courts Impose More Than $300 Million In Civil Penalties Against Ethicon

Ethicon's pelvic mesh ultimately became the subject of this litigation. In 2016, the California Attorney General filed an enforcement action against Ethicon alleging that it violated the Unfair Competition Law (UCL) and False Advertising Law (FAL) by distributing untrue or misleading communications about its pelvic mesh products. Pet. App. 114a-115a.

At trial, California surgeon-witnesses who implanted mesh explained they knew about the relevant risks and that the IFU statements were not deceptive. *See* 39RT6248-6251 (urogynecologist testifying about the risks of mesh surgery that OB/GYN residents learn about when doing a rotation in female pelvic medicine and reconstructive surgery); 54RT9077-9078, 54RT9082 (urologist explaining, "[a]nyone who is doing pelvic surgery knows the risks of pelvic surgery"); 41RT6668 (urogynecologist stating that "urinary retention is definitely a known risk" of SUI pelvic mesh implantation); 41RT6681-6683 (urogynecologist explaining that he learned about risks of vaginal surgery in medical school and surgical residency); 41RT6818 (urogynecologist stating that implanting mesh devices carried many of the same risks as other vaginal surgeries, which he learned about in residency).

The trial court nevertheless held that Ethicon's pelvic mesh marketing materials and disclosures were UCL and FAL violations. It found that the materials contained false and misleading statements that did not disclose the full scope and severity of mesh-specific risks. Pet. App. 159a-160a. The court concluded that this was likely to deceive doctors. Pet. App. 159a, 215a. It relied heavily on the text of the materials themselves, and found that doctors would rely on these materials. The court also credited testimony from doctors who never implanted mesh, or who did so outside the state of California. *E.g.*, Pet. App. 167a-168a, 204a-206a, 212a-213a. Further, the court found that Ethicon's experts had an incomplete understanding of the sources of the relevant risks. Pet. App. 208a-210a. Further, the court found that Ethicon's patient-facing materials were "likely to deceive." Pet. App. 190a, 224a, 242a.

The trial court then evaluated the number of separate violations—each subject to a civil penalty of up to $2,500. Pet. App. 242a; Cal. Bus. & Prof. Code §§ 17206, 17536. Neither statute defines what constitutes a single violation, or offers any guidance as to how a court should make that decision. *See* Pet. App. 86a. It is simply "up to the [c]ourt to determine what constitutes a violation for the purpose of calculating penalties." Pet. App. 220a-221a (citation and quotation marks omitted); *accord* Pet. App. 86a ("[C]ourts must decide what amounts to a violation on a case-by-case basis."). Further, violation counting does not require any assessment of harm to individual consumers. *Infra* 28, 33-35.

The trial court counted as individual violations every single printed piece of marketing *estimated* to have been shipped to California—without regard to whether such materials were actually delivered, read, relied-upon, or resulted in harm. *See* Pet. App. 227a-234a, 92a-93a. For example, the court found 52,176

UCL and FAL violations based on an estimate of print marketing materials shipped into the State from 2008 to 2011. Pet. App. 228a-229a. The estimate was based on an extrapolation of *one* sales representative's ordering patterns to all other California sales representatives, assuming that all representatives ordered materials at the same monthly pace. Pet. App. 228a; *see* 32RT4582.

The court also determined that Ethicon shipped 8,108 print marketing materials to California between January 2012 and February 2017, based on Ethicon's discovery responses. It concluded that every single piece of material sent into the State constituted both a UCL violation and an FAL violation—regardless of whether the marketing materials were ever actually distributed or seen by anyone. Pet. App. 227a-228a.

Further, the court assessed 45,000 additional separate violations based on physicians' and hospitals' alleged *re*-distribution of material Ethicon prepared for public relations purposes—regardless of whether the physicians or hospitals actually used any of Ethicon's content in the hospital's newsletters and other publications. *See* Pet. App. 242a-243a. Ethicon sent public relations kits to hospitals and physicians, which contained various materials that recipients could use however they wished to develop their own materials. 32RT4541; Pet. App. 286a; 24AA5056; 24AA5060; 35RT5338. The court used Ethicon's estimates of the circulation of newsletters and publications distributed by those hospitals, without any evidence regarding what Ethicon-produced content, if any, was actually disseminated or ever read. *See* 32RT4541;

35RT5332-40. The State's expert simply used estimates from an Ethicon tracker reflecting that the hospitals' communications were related to mesh public relations. *See* 35RT5341; Pet. App. 242a.

The court also counted every single in-box IFU that Ethicon was estimated to have sent into California during the statutory period—66,343 statutory violations. *See* Pet. App. 226a-227a, 87a-88a. And it counted each oral communication estimated to have been made by Ethicon's sales representatives during things like company-sponsored meals and health fairs—again without regard to what Ethicon's representatives might actually have said. Pet. App. 237a-241a.

In total, the court found that Ethicon committed 153,351 UCL violations and 121,844 FAL violations. Pet. App. 243a. As for the penalty per violation, the court recognized that it had wide discretion under California law to impose a penalty of "up to $2,500." Pet. App. 242a. Reasoning that a significant penalty was appropriate, the trial court imposed a penalty of $1,250 for each violation—with no differentiation among the type or severity of violations. Pet. App. 243a. The trial court thus imposed $343,993,750 in civil penalties against Ethicon. Pet. App. 243a.

The trial court denied the State's request for injunctive relief. Pet. App. 109a-112a. It highlighted a "letter from over 70 physicians lauding defendants' mesh products and stating their grounds for supporting the right to access them." Pet. App. 111a. It expressed concern that an injunction might prompt Ethicon to withdraw its products from California. *Id.*

Ethicon appealed the liability findings and civil penalty award. The California appellate court largely affirmed the trial court's decision, but reversed in one respect. It held that the trial court erred by penalizing Ethicon for oral marketing communications when there was "no evidence" of what Ethicon's agents said. Pet. App. 3a-4a; *see* Pet. App. 66a-69a. The appellate court thus reversed violations based on bare numbers of estimated visitors at a health expo, company-sponsored meals, and sales representative "detailing" (i.e., on site visits to healthcare providers)—when the court lacked any detail about whether anyone could possibly have been misled at those events. Pet. App. 69a.

The appellate court otherwise affirmed the violations count. It acknowledged, however, that the trial court counted thousands of violations based on print marketing materials never proven to have reached consumers. Pet. App. 92a-93a. The appellate court said that such proof "would have been desirable," but that counting these communications as violations was within the trial court's "discretion" under the circumstances. Pet. App. 92a-93a.

Accordingly, the Court of Appeal adjusted the total civil penalty to $302,037,500, reflecting a revised violation count of 134,386 UCL violations and 107,244 FAL violations. *See* Pet. App. 69a.

The California Supreme Court denied Ethicon's petition for review. Pet. App. 544a.

REASONS FOR GRANTING THE WRIT

I. The Court Should Grant Certiorari To Clarify That Robust Fair Notice Requirements Apply To UDAP Statutes.

The Court should grant certiorari to clarify that a robust due process fair notice standard protects businesses subject to UDAP statutes like California's.

"A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). That "demand of fair notice" is "[p]erhaps the most basic of due process's customary protections." *Sessions v. Dimaya*, 138 S. Ct. 1204, 1225 (2018) (Gorsuch, J., concurring in part and concurring in the judgment). The Due Process Clause therefore requires statutes "to provide a person of ordinary intelligence fair notice of what is prohibited." *Fox Television Stations*, 567 U.S. at 253 (quoting *United States v. Williams*, 553 U.S. 285, 304 (2008)). It likewise requires notice of the severity of the potential sanction. *See Johnson v. United States*, 576 U.S. 591, 596 (2015) (applying due process protections to "statutes fixing sentences").

This Court has applied those protections to both civil and criminal laws. *See A.B. Small Co. v. Am. Sugar Refining Co.*, 267 U.S. 233, 239 (1925) (holding that the criminal/civil distinction "is not an adequate distinction" for purposes of the fair notice doctrine); *Giaccio, v. Pennsylvania*, 382 U.S. 399, 402 (1966) (the fair notice requirement applies whether a statute is "labeled 'penal' or not"). That approach is consistent with early American practice. *See McConvill v. Mayor and Aldermen of Jersey City*, 39 N.J.L. 38, 42 (1876) ("all laws" "ought to be expressed in such a manner as that its meaning may be unambiguous"); *Commonwealth v. Bank of Pennsylvania*, 3 Watts & Serg. 173, 177, 1842 WL 4682, *4 (Pa. 1842) (voiding as vague a statute describing the number of votes per shares of stock); *Drake v. Drake*, 15 N.C. 110, 115 (1833) ("Whether a statute be a public or a private one, if the terms in which it is couched be so vague as to convey no definite meaning … it is necessarily inoperative.").

This Court has, however, at times stated that some laws imposing civil penalties are subject to less exacting fair notice standards. *See Winters v. New York*, 333 U.S. 507, 515 (1948) ("The standard[] of certainty in statutes punishing for offenses is higher than in those depending primarily upon civil sanction for enforcement."); *Vill. of Hoffman Estates v. Flipside*, 455 U.S. 489, 498-99 (1982) ("The degree of vagueness that the Constitution tolerates … depends in part on the nature of the enactment," with "greater tolerance of enactments with civil rather than criminal penalties.").

The degree of fair notice scrutiny applicable to different types of laws remains a critical open question. At least certain types of civil laws—including challenges implicating First Amendment concerns and immigration consequences—will be closely scrutinized. *See Fox Television Stations*, 567 U.S. at 253-54 (applying robust vagueness standard to "ensure that ambiguity does not chill protected speech"); *Grayned v. City of Rockford*, 408 U.S. 104, 109 (1972) (similar);

Dimaya, 138 S. Ct. at 1213 (plurality opinion) (applying "the most exacting vagueness standard" given "'the grave nature of deportation'"). But this Court has not yet ruled on what due process strictures apply to state statutes that, like California's UDAP statutes, give state attorneys general vast discretion to seek hundreds of millions of dollars in civil penalties related to commercial speech—and which may involve criminal penalties. Clarity regarding the applicable standards is very much needed.

State courts have repeatedly held that UDAP statutes are entitled to only weak vagueness scrutiny. They have brushed off such statutes as "regulatory statutes governing business activities," permitting "[g]reater leeway … in applying the fair notice test." *Mother & Unborn Baby Care of N. Texas, Inc. v. State*, 749 S.W.2d 533, 540-41 (Tex. App. 1988) (quoting *Papachristou*, 405 U.S. at 162); *see State ex rel. Nixon v. Telco Directory Publ'g*, 863 S.W.2d 596, 600 (Mo. 1993) (classifying a UDAP statute as "an economic regulation" and reasoning that because the State sought civil penalties, a "less restrictive" vagueness standard applied); *Dep't of Legal Affairs v. Rogers*, 329 So.2d 257, 264 (Fla. 1976) (explaining, when analyzing purported vagueness of UDAP statute, that "regulatory statutes governing business activities" are entitled to "greater leeway" (quoting *Papachristou v. Jacksonville*, 405 U.S. 156, 162 (1972))); *State v. Ralph Williams' Nw. Chrysler Plymouth, Inc.*, 510 P.2d 233, 242 (Wash. 1973) (similar); *but see State v. Shaw,* 847 S.W.2d 768, 775 (Mo. 1993) (applying more robust vagueness standard in UDAP case involving criminal penalties). At least one state court has expressly rejected arguments that UDAP statutes, because they are capable of reaching constitutionally protected speech or because they are punitive in nature, must be "held to a stricter standard of definiteness." *Scott v. Ass'n for Childbirth at Home, Int'l*, 430 N.E.2d 1012, 1016-18 (Ill. 1981).

This Court's intervention is necessary to make clear that—contrary to those holdings—robust due process vagueness scrutiny applies to these statutes. As Justice Gorsuch has explained, the penalties imposed by civil laws can be just as severe as—and sometimes more severe than—criminal punishments. *Dimaya*, 138 S. Ct. at 1229 (Gorsuch, J., concurring in part and concurring in the judgment). That is certainly true of the exorbitant penalties that states are exacting under these UDAP statutes. There is "no good" reason why due process would permit a legislature to speak less clearly in those contexts. *Id.* at 1231.

Massive UDAP penalties are all the more problematic because they risk chilling protected commercial speech. As noted, the Court has repeatedly held that statutes raising First Amendment concerns are entitled to greater protection. *See Fox Television Stations*, 567 U.S. at 254; *Grayned*, 408 U.S. at 109. To be sure, misleading commercial speech and "commercial speech related to illegal activity" is not protected. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 563-64 (1980). However, given the statute's broad language, companies cannot know how violations will be assessed. *See infra* 24-28. And given the broad scope of the UDAP statutes, it is hard to isolate unprotected speech from protected speech. Indeed, the complex analysis of what speech is "likely to deceive" under California's UDAP statutes has been deemed outside of the "type of ordinary factfinding assigned to a jury." *Nationwide Biweekly Admin., Inc. v. Super. Ct.*, 462 P.3d 461, 476 (Cal. 2020). The threats of expansive and uncertain UDAP liability "both chill and tax socially desirable manufacturer/marketer communication to consumers." Henry N. Butler & Jason S. Johnston, *Reforming State Consumer Protection Liability: An Economic Approach*, 2010 Colum. Bus. L. Rev. 1, 35; *see also id.* at 42-43 (providing examples of consumer protection acts chilling communications with consumers). A robust fair notice standard is critical to businesses being able to anticipate when their speech can lead to massive civil penalties.

Further, at least in California, a false advertising violation can result in *criminal* penalties. The statute provides, "[a]ny violation of the provisions of this section is a misdemeanor punishable by imprisonment in the county jail not exceeding six months, or by a fine not exceeding two thousand five hundred dollars ($2,500), or by both." Cal. Bus. & Prof. Code § 17500. Thus, the conduct that will trigger civil and criminal liability is identical. It is nonsensical to apply a different standard, leading to a different outcome, in one context versus the other. *See Dimaya*, 138 S. Ct. at 1217 (plurality opinion) (explaining that a statute with applications in criminal and noncriminal contexts must be interpreted consistently across contexts); *H.J. Inc. v. Nw. Bell Tel. Co.*, 492 U.S. 229, 255 (1989) (Scalia, J., concurring) (explaining that a statute with "criminal applications … must, even in its civil applications, possess the degree of certainty required for criminal laws"); *FCC v. Am. Broad. Co.*, 347

U.S. 284, 296 (1954) (refusing to interpret statute to have one meaning in criminal cases and another meaning in agency enforcement actions).

This Court should grant certiorari and hold that UDAP statutes, such as California's, are subject to robust fair notice protections.

II. California Law Failed To Provide Fair Notice Of The Severity Of The Penalty.

The California courts assessed tens of thousands of violations based on communications not proven to have reached consumers. That included (1) every Ethicon mesh brochure shipped to California sales representatives (regardless of whether the brochure was distributed); and (2) the estimated circulation of third party hospital newsletters (regardless of whether the newsletters contained *any* information from Ethicon). In other words, California courts are now counting separate violations based on communications that may not have been seen or even received by anyone. Ethicon lacked fair notice that it would be penalized for communications that never occurred.

A "punishment fails to comply with due process if the statute … under which it is obtained fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement." *Fox Television Stations*, 567 U.S. at 253 (internal quotation marks omitted). As this Court has explained, vague laws offend several important constitutional values. "First, because we assume that man is free to steer between lawful and unlawful conduct, we insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly." *Grayned*, 408 U.S. at 108. Second, "[a] vague law impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application." *Id.* at 108-09. Third, where, as here, "a vague statute abut(s) upon sensitive areas of basic First Amendment freedoms, it operates to inhibit the exercise of (those) freedoms." *Id.* at 109 (alterations in original) (internal quotation marks omitted).

The Due Process Clause requires fair notice not only of prohibited conduct, but also of "the severity of the penalty that a State may impose." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 417 (2003) (quoting *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 (1996)); *see also Karem v. Trump*, 960 F.3d 656, 665 (D.C. Cir. 2020) (explaining that Due Process Clause required journalist to have fair notice of the magnitude of the sanction—suspension of special press credentials—that could result from his conduct). Normally, a defendant is provided notice of the potential scope and severity of a civil penalties award from a statute itself—the text ordinarily makes that exposure clear. When that text lacks sufficient guidance, however, such notice evaporates. Robust due process protections against vague and arbitrarily-enforced standards are thus equally critical in the penalty context. *See Johnson*, 576 U.S. at 596 (applying due process protections to "statutes fixing sentences").

Here, Ethicon lacked fair notice of how the California courts would count statutory violations—and therefore lacked fair notice of the severity of the award. The courts punished Ethicon separately for every brochure, mailer, and sales aid containing statements "likely to deceive" doctors and/or consumers, regardless of whether those materials ever reached their target audience. The courts also punished Ethicon for the estimated circulation of hospitals' communications that may have included information from Ethicon PR materials. A "person of ordinary intelligence" would have no "fair notice" that it could violate California's UDAP statutes every time it shipped a marketing brochure to California—without any finding that this brochure reached a consumer. Or that it would be punished for its communications to hospitals, with a separate penalty accumulating for every time a hospital *may have* circulated a newsletter that *may have* included information that the company provided. The resulting penalty count was unpredictable and resulted in arbitrary enforcement against Ethicon.

To start, California's UDAP statutes fail to cabin the court's discretion in counting civil penalties. To the contrary, each statute provides penalties for "violation[s]"—without defining what a violation is. *See* Cal. Bus. & Prof. Code § 17206(a) (under the UCL, anyone who "engages, has engaged, or proposes to engage in unfair competition shall be liable for a civil penalty not to exceed two thousand five hundred dollars ($2,500) for each violation"); *id.* § 17500 (any FAL "violation" is a "misdemeanor punishable by imprisonment in the county jail not exceeding six months, or by a fine not exceeding two thousand five hundred dollars ($2,500), or by both"); *id.* § 17536(a) (any person who violates the FAL "shall be liable for a civil penalty not to exceed two thousand five hundred dollars ($2,500) for each violation"). Thus, "courts must decide what amounts to a violation on a case-by-case basis." Pet. App. 86a.

Any business reading the statute as a whole would reasonably conclude that—at minimum—a statement must be shared with the public before being deemed a "violation." For instance, the FAL bars a business from "mak[ing] or disseminat[ing] … before the public" any "untrue or misleading" statement. Cal. Bus. & Prof. Code § 17500. A statement cannot violate this law if it is not "before the public." Similarly, the UCL bars "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200. A statement cannot be "unfair," "deceptive," or "misleading"—nor can it be considered "advertising"—if it never reaches an audience. To the contrary, a court must ask whether "members of the public are likely to be deceived." *Shaeffer v. Califia Farms, LLC*, 258 Cal. Rptr. 3d 270, 277 (Cal. Ct. App. 2020) (quoting *Kasky v. Nike, Inc.*, 45 P.3d 243, 250 (Cal. 2002)). The answer is unequivocally "no" unless that statement is shared with the audience.

The caselaw—up until now—therefore required that marketing materials reach the public before being deemed violations. California courts looked to the number of people who saw or heard the alleged misrepresentation. *See People v. JTH Tax, Inc.*, 151 Cal. Rptr. 3d 728, 755 (Cal. Ct. App. 2013); *People v. Super. Ct. (Olson)*, 157 Cal. Rptr. 628, 639 (Cal. Ct. App.

1979). Or the number of sales triggered by the alleged misrepresentation. *See People v. Toomey*, 203 Cal. Rptr. 642, 656-57 (Cal. Ct. App. 1984). Or the number of days on which the misrepresentations were online. *See People v. Overstock.com, Inc.*, 219 Cal. Rptr. 3d 65, 85-86 (Cal. Ct. App. 2017). Thus, the court assessed penalties based on the total circulation of an alleged misstatement only if that misstatement was actually sent to consumers. *See People v. Morse*, 25 Cal. Rptr. 2d 816, 826 (1993) (counting as separate violations "highly individualized solicitations" that were part of a "direct mail campaign").

In rejecting an argument that a previous version of the FAL was vague for failure to identify how to count violations, the California Court of Appeal specified that trial courts should account for, among other things, the "number of victims." *People v. Witzerman*, 105 Cal. Rptr. 284, 291 (Cal. Ct. App. 1972). It left open the possibility that unreasonable or "arbitrary" applications of this provision would be unconstitutional. *Id.*

Now, however, the California courts have unmoored themselves from these constraints on counting violations. What exists today is an open ended, case-by-case standard that deprives businesses of fair notice of how violations will be assessed and penalties imposed. The courts' accounting of separate "violations" here included 68,392 violations for print marketing materials sent to sales representatives in California—regardless of whether those materials ever reached consumers. Pet. App. 228a-229a, 92a-93a. For some years, the State's expert simply extrapolated from a single sales representative's testimony and applied it to the entire sales force—guessing how many brochures they collectively ordered to the state. Pet. App. 228a.

The State's expert did not "account for brochures that were ordered but not distributed"—which the Court of Appeal acknowledged "would have been desirable." Pet. App. 92a-93a. This is striking, given that the sales representative whose ordering history the expert relied on stated that he did not give doctors or hospitals every piece of material he ordered, and that he threw away the materials he did not distribute. 35RT5357-58. Further, the uncontroverted testimony from Ethicon's person most qualified on sales-related practices was that she did not "hand out or distribute every brochure that [she] ordered," and that she maintained a large "back stock" of undistributed materials that "filled up two recycling bins." 26RT3458-59. The result is arbitrary and unpredictable enforcement: Ethicon was inevitably punished for "misleading" communications that reached no one, and which never could have been punished as standalone violations.

The pattern followed for public relations kits. Ethicon distributed kits to hospitals with information that they could choose to include in their newsletters and other mailings. 24AA5039-40, 24AA5056, 24AA5060. The court simply penalized Ethicon for the total estimated circulation of hospital newsletters that Ethicon tracked for mesh publicity purposes—publications distributed to the hospitals' large mailing lists. It imposed over $56 million in penalties for that estimated circulation, without any proof of whether those newsletters contained information from Ethicon's press kits—let alone deceptive statements. *See supra* 14-15; Pet. App. 242a-243a.

The statute did not give Ethicon fair notice that it would be found "likely to deceive" consumers with marketing materials not established to have reached consumers at all. Rejecting Ethicon's argument that it lacked notice of the potential severity of the penalties, the Court of Appeal reasoned that "judicial authorities have long discussed the broad discretion courts possess when it comes to defining and calculating the number of UCL and FAL violations." Pet. App. 98a-99a. But longstanding *awareness* of a lack of guidance does not render it any less problematic. And the California court opinion touting the lack of standards further demonstrates that the state courts are not going to fix this problem themselves—these courts will continue to come up with ad hoc methods for counting penalties that lack predictability or consistency.

Now, the individual UDAP violations—already untethered from basic tort law protections of per-violation reliance and harm—are not even tied to *theoretical* harm to consumers: communications not proven to have reached consumers are not even "likely to deceive" them. Because Ethicon did not have reason to believe that such communications would be deemed violations, it lacked notice of the severity of the penalties in this case. And courts applying this expansive interpretation going forward will have little to constrain their decision-making. This Court should grant certiorari to ensure there are meaningful constitutional limits on a state's ability to impose civil penalties against businesses under vague UDAP statutes.

III. Certiorari Is Warranted Because The Question Presented Is Of Recurring Nationwide Significance.

This case is a vivid illustration of a serious nationwide problem: vague UDAP statutes that allow circumvention of important established tort law guardrails. These statutes lead to the deprivation of basic property rights without due process of law.

A. Vague UDAP statutes threaten fundamental property rights.

Vague proscriptions characterize UDAP laws across the country—and plague well-intentioned businesses. "Broad, flexible prohibitions of unfair and deceptive practices are the hallmark of UDAP laws." National Consumer Law Center, *Consumer Protection in the States: A 50-State Evaluation of Unfair and Deceptive Practices Laws* 1 (Mar. 1, 2018), https://tinyurl.com/2p9s4w9b. The "vagueness" of terms like "unfair" and "deceptive" in UDAP statutes "provides substantial power to state AGs." U.S. Chamber Inst. for Legal Reform, *Unfair Practices or Unfair Enforcement?: Examining the Use of Unfair and Deceptive Acts and Practices (UDAP) Laws by State Attorneys General* 1 (Oct. 2016), https://tinyurl.com/y7nxavbr. Such laws allow for post-hoc liability determinations.

Congress confronted a similar vagueness problem when it passed the Federal Trade Commission Act ("FTC Act"), which declares unlawful "unfair or deceptive acts or practices." 15 U.S.C. § 45(a)(1). To ensure that businesses have reasonable notice of their exposure to massive penalties, the FTC Act established a bipartisan Commission, 15 U.S.C. § 41, to prescribe rules defining "with specificity" unfair or deceptive acts or practices and to issue interpretations and policy statements regarding unfair or deceptive acts or practices, 15 U.S.C. § 57a(a)(1). By contrast, "California has no administrative agency equivalent to the Federal Trade Commission," *Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 973 P.2d 527, 543 (Cal. 1999), and no constraining regulations. The same is true in states across the country. *See* Cary Silverman & Jonathan L. Wilson, *State Attorney General Enforcement of Unfair or Deceptive Acts and Practices Laws: Emerging Concerns and Solutions*, 65 Univ. of Kan. L. Rev. 209, 213-14 (2017) (explaining that the FTC Act provides businesses more protections than UDAP statutes typically do).

Historically, the remedies available under broad state consumer protection statutes were principally equitable. *See* James Cooper & Joanna Shepherd, *State Unfair and Deceptive Trade Practices Laws: An Economic and Empirical Analysis*, 81 Antitrust L. J. 947, 953-55 (2017). The main relief available was an injunction, and civil penalties were authorized only as an incidental remedy, if at all. In California, for example, civil penalties were not available under the UCL and FAL until decades after those statutes were initially adopted. *See Nationwide Biweekly Admin.*, 462 P.3d at 468, 474. UDAP statutes in other states likewise initially authorized injunctions and were only later amended to authorize civil penalties. *See, e.g.*, *Ralph Williams' Nw. Chrysler Plymouth,* 510

P.2d at 239 (relief under Washington UDAP statute was originally limited to injunction and penalty for violating injunction). The process of adjudicating the injunction gave defendants substantial notice of what the law requires going forward. After all, injunctive relief is quintessentially forward-looking, and binds a party prospectively, with some degree of specificity. *See, e.g.*, Fed. R. Civ. P. 65(d). But the rise of free-standing civil penalties made vague UDAP statutory language even more problematic. Civil penalties punish past conduct. When imposed pursuant to the vague, open-ended terms in UDAP statutes, they do so without fair notice.

Currently, "[a]ll states except [one]" have UDAP statutes that "allow the state agency to seek civil penalties for initial violations." *Consumer Protection in the States*, *supra*, at 28. Today's UDAP statutes empower states to seek multi-million-dollar penalties, without providing advance notice or first demanding that the purportedly deceptive practices cease. And many states have laws like California's, which give businesses little to no advance notice of how many "violations" a particular course of conduct will comprise. *See* Silverman & Wilson, *supra*, at 265 (noting "the vagueness" of the term "per violation" in UDAP statutes). By breaking one course of conduct into thousands of separate violations and "creatively multiplying" the available penalties by those alleged violations, the state "can transform a single act into a multimillion dollar penalty." *Unfair Practices*, *supra*, at 3.

Failing to define how to count violations can have extreme results. States permit civil penalties ranging from $1,000 to $50,000 *per violation*. *Consumer Protection in the States*, *supra*, at 2, 31. The range of discretion is huge. And states frequently "aggregate" the available penalty amount "'per violation,' multiplying it for each letter mailed, sales call made, prescription filled, … product or service sold," or website click from an internet browser. Silverman & Wilson, *supra*, at 210. Through such creative accounting, amassing hundreds of thousands of violations, even per-violation penalties at the middle or low end of the available statutory range "can still reach an extraordinary sum when aggregated." *Id.* at 241. Consequently, "businesses are exposed to extraordinary penalties for a single action." *Id.* at 242.

States' "requests for statutory penalties on a per-violation basis" can produce vast "cumulative penalt[ies] grossly disproportionate to both the injury [the state] has suffered and the seriousness of [the defendant's] alleged misconduct." *In re Zyprexa Prods. Liab. Litig.*, 671 F. Supp. 2d 397, 463 (E.D.N.Y. 2009). Illustrating the enormous awards that can result, a Hawaii court recently imposed an $834 million penalty against the pharmaceutical companies who marketed the medication Plavix. *State ex rel. Connors v. Bristol-Myers Squibb Co.*, No. 14-1-0708-03, 2021 Haw. Trial Order LEXIS 2, at *80-81 (Haw. Cir. Ct. 1st Cir. Feb. 15, 2021). The South Carolina courts likewise imposed a $124 million penalty against a pharmaceutical company for its labeling and marketing of an antipsychotic drug. *State ex rel. Wilson v. Ortho-McNeil-Janssen Pharms., Inc.*, 777 S.E.2d 176 (S.C. 2015). Notably, the South Carolina Supreme Court acknowledged that there was an "absence of significant actual harm resulting from [the company's] deceptive conduct"—despite the nine-figure penalty. *Id*. at 204. And even when these cases do not go to trial, the broad liability under state UDAP statutes creates extreme pressure for businesses to settle. For example, in litigation regarding its marketing of the antipsychotic drug Zyprexa, Eli Lilly settled UDAP claims with dozens of state AGs for a total of over $250 million. *Unfair Practices*, *supra*, at 29.

These massive UDAP penalties, and the settlements coerced by the threat of such enormous penalties, demonstrate how these vague UDAP statutes are an ever-present threat to businesses. Businesses lack advance notice of what will be considered a separate violation. And they lack notice of how much they will pay for each violation—let alone the aggregate amount they will pay for all violations. Enforcing due process limits with respect to the civil UDAP penalties would be an important step toward protecting businesses' basic property rights in the face of these far-reaching and poorly-defined regulatory schemes.

Imposing reasonable due process limits is particularly important to protecting property rights because UDAP statutes allow the circumvention of the essential substantive guardrails of state tort law. State tort laws require proof of reliance, causation, and harm to establish misrepresentation or fraud. *See, e.g.*, Restatement (Third) of Torts: Liability for Economic Harm §§ 5(1), 9, 11; Restatement (Second) of Torts §§ 525, 537. Similarly, causation and harm are key parts of products liability law. *See* Restatement (Third) of Torts: Products Liability §§ 1, 2, 15. These elements of a tort claim serve critical functions. Reliance and causation requirements protect defendants by limiting their liability to acts that actually caused real, foreseeable harm to the plaintiff. *See* John C.P. Goldberg, Anthony J. Sebok, & Benjamin C. Zipursky, *The Place of Reliance in Fraud*, 48 Ariz. L. Rev. 1001, 1008-09 (2006); Restatement (Third) of Torts: Liability for Economic Harm § 11, cmt. a; Restatement (Third) of Torts: Liability for Economic Harm § 12; *see also* Butler & Johnston, *supra*, at 84 (describing reliance and causation as "protections"). Courts are not guessing about whether an act will deceive anyone—or how many people might be affected—because the plaintiff must demonstrate that fact as part of her affirmative case. Harm requirements also tether punitive damages awards, providing notice of the total exposure a defendant faces. *See State Farm*, 538 U.S. at 426 (holding that punitive damages must be "proportionate to the amount of harm to the plaintiff and to the general damages recovered").

UDAP statutes largely eliminate these essential protections in actions initiated by the state attorneys general. In ordinary tort actions, a plaintiff can recover only by proving that the defendant caused her harm. But UDAP statutes lack that limitation with respect to AG enforcement actions. Instead, they permit "civil penalties regardless of whether anyone was actually misled or otherwise harmed." *Unfair Practices, supra*, at 3. All that is required is pointing to a business practice that "had the *tendency* to deceive or was capable of misleading someone." *Id.* at 23; *see also* Butler & Johnston, *supra*, at 82 (litigation under state consumer protection acts "is stacked in favor of plaintiffs" because the acts "limit the common law protections that reflected a balance of seller and consumer interests”). Untethered from individualized proof of harm and causation, each company’s potential exposure is extremely unpredictable. This only compounds the uncertainty created by the court’s extraordinarily high amount of discretion in counting violations. At minimum, this Court should enforce the requirements of fair notice with respect to civil penalties when a statute eliminates the protections of tort law.

Further exacerbating the lack of traditional tort protections, many UDAP actions in other states brought under the auspices of the state attorney general’s office are in fact driven directly or indirectly by the private plaintiffs’ bar. These actions “are typically not sparked by consumer complaints, but are developed by private lawyers retained by AGs to pursue the litigation on the state’s behalf.” Silverman & Wilson, *supra*, at 209. Actions of this sort “d[o] not originate with a government-identified need to protect consumers. Rather, private attorneys develop the theories of liability, approach state AGs, and then litigate the state’s enforcement action in exchange for a contingency fee.” *Id*. at 217. While California does not follow this approach, the prevalence of such practices—and the expansive litigation it generates without the normal protections of tort law—highlights the necessity of imposing constitutional limits on state deprivations of property.

In all, UDAP statutes have become standardless vehicles for expansive litigation that lack critical protections for defendants’ property rights, and make it extraordinarily difficult to predict the potential severity of the penalties. This Court should grant review to impose constitutional due process limits on violation counting, as an important step toward addressing this broader problem.

B. The unpredictable and arbitrary deprivation of property by state UDAP statutes imposes unacceptably high costs on business, investment, innovation, and consumers.

The uncertainty and enormous risks surrounding UDAP penalties discussed above will have the expected natural consequences—deterring investment and innovation. Those consequences are most severe for those in heavily regulated industries. This includes businesses involving medical technology, pharmaceuticals, and life sciences—which must already run a gauntlet of federal legislation, agency regulations, FDA rules, international standards, state legislation, state tort law, and other rules imposed in 50 different state jurisdictions.

To develop and bring critical lifesaving products to market in a complex, highly regulated environment, companies like Ethicon must be able to evaluate their potential exposure to regulatory actions, tort liability, and civil penalties—and calibrate their business strategies in advance. *See Landgraf v. USI Film Prods.*, 511 U.S. 244, 266 (1994) ("[C]reativity in … commercial … endeavors is fostered by a rule of law that gives people confidence about the legal consequences of their actions."). That is already extraordinarily difficult and complex: UDAP actions "often target practices already regulated by government agencies charged with protecting the public." Silverman & Wilson, *supra*, at 209. For example, states sometimes "use[] UDAP laws to step into the shoes of the U.S. Food and Drug Administration to regulate the marketing of prescription drugs or impose fines that are not warranted under federal law." *Id*. at 209-10. Indeed, Mississippi is using its UDAP statute to seek more than $65 billion for a company's failure to include a warning that the FDA expressly rejected. *See Johnson & Johnson v. Fitch*, 315 So.3d 1017, 1019 (Miss. 2021) (Mississippi is seeking $10,000 for each violation—the alleged failure to include certain warnings on product labels); Expert Report of Donald M. May at 4, *State ex rel. Fitch v. Johnson & Johnson*, No. 25CH1:14-cv-01207 (Miss. Chancery Ct. Sept. 1, 2022), Doc. No. 406-1 (State's expert calculating that at least 6,501,144 products were sold during relevant time period); Memorandum of Law in Opposition to Motion for Summary Judgment at 13, *State ex rel. Fitch*, 25CH1:14-cv-01207 (Miss. Chancery Ct. Feb. 28, 2018), Doc. No. 269 (State asserting that every sale of the product would constitute a separate violation). While some states exempt from the coverage of UDAP laws conduct that is permitted, approved, or specifically authorized by state or federal agencies, courts are "inconsistent … in their interpretation and application" of these exemptions. Silverman & Wilson, *supra*, at 225.

Adding an extra layer of uncertainty through arbitrary and unpredictable penalties harms consumers, investment, and economic growth. Left unchecked, the possibility of enormous civil penalties can diminish venture financing and capital investment, especially in the life sciences sector, which impedes the development of new medical technologies. *See* Amicus Letter of California Life Sciences at 3-4, *Johnson & Johnson v. People*, No. S274680 (Cal. June 16, 2022). In the labeling context, such uncertainty can also lead to over-warning to curtail risk. *See* Mark Geistfeld, *Inadequate Product Warnings and Causation*, 30 Univ. of Mich. J. of L. Reform 309, 310 (1997) (describing concern that "overenforcement" of failure to warn "provides an incentive to sellers to over-warn"); Lars Noah, *The Imperative to Warn: Disentangling the* Right to Know *from the* Need to Know *about Consumer Product Hazards*, 11 Yale J. on Regul. 293, 375 (1994) (penalties for under-warning incentivize providing "extremely detailed and comprehensive warnings rather than meaningful cautionary statements about only truly important risks"). But such practices undermine the FDA's authority to determine what warnings to require and what to leave to the discretion of manufacturers. *See* Douglas G. Smith, *A Shift in the Preemption Landscape?*, 87 Tenn. L. Rev. 213, 244 (2019) (underapplication of the preemption doctrine may lead to over-warning). Over-warning also harms consumers by diluting the important warnings they need to focus on. *See* 73 Fed. Reg. 2848, 2851 (Jan. 16, 2008) ("Overwarning has the effect of not warning at all.").

Further, the uncertainty imposes special costs where, as here, the penalties impose unpredictable punishments for speech. It is well established that "firms often refrain from informative advertising out of fear of consumer protection liability." Cooper & Shepherd, *supra*, at 974. "When this happens, consumers suffer again by either making less-informed purchases or by incurring costs to seek out relevant product information that is no longer supplied to them." *Id.* at 974-75.

In all, these laws create vast uncertainty for companies trying to inform consumers about their products. Businesses have a right, at minimum, to notice of when their statements will trigger hundreds of millions of dollars in civil penalties, and predictability and consistency in how those penalties are applied. It is vitally important that this Court make clear that the Due Process Clause requires fair notice before a state may exercise its authority to impose civil penalties via UDAP enforcement.

CONCLUSION

For the foregoing reasons, the petition should be granted.

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Date November 10, 2022